

PAT

Date: January 12, 1999

414 Rec'd PCT/PTO 12 JAN 1999

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**TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 USC 371**

09/230001

International Application No.: PCT/NL97/00404
International Filing Date: July 9, 1997
Priority Date Claimed: July 12, 1996
Title of Invention: STERILISATION APPARATUS
Applicant(s) for DO/EO/US: Evert Bastiaan De Heus

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. (X) This is a **FIRST** submission of items concerning a filing under 35 USC 371.
2. (X) This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).
3. (X) A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
4. (X) A copy of the International Application as filed (35 USC 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
5. (X) Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. (X) have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.

Items below concern other document(s) or information included:

6. (X) A FIRST preliminary amendment.
7. (X) International Application as published.
8. (X) A return prepaid postcard.

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9. (X) The following fees are submitted:

				FEES
BASIC FEE				\$840
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total Claims	15 - 20 =	0 ×	\$18	\$0
Independent Claims	1 - 3 =	0 ×	\$78	\$0
Multiple dependent claims(s) (if applicable)			\$260	\$0
TOTAL OF ABOVE CALCULATIONS				\$840
TOTAL FEES ENCLOSED				\$840

10. (X) The fee for later submission of the signed oath or declaration set forth in 37 CFR 1.492(e) will be paid upon submission of the declaration.
11. (X) A check in the amount of \$840 to cover the above fees is enclosed.
12. (X) The Commissioner is hereby authorized to charge only those additional fees which may be required to avoid abandonment of the application, or credit any overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

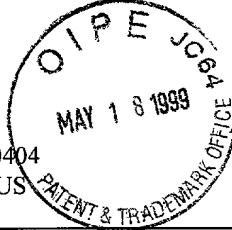
KNOBBE, MARTENS, OLSON & BEAR, LLP
620 Newport Center Drive
Sixteenth Floor
Newport Beach, CA 92660


Signature

Daniel E. Altman
Printed Name

34,115
Registration Number

DEA-3725 kc
011199



VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL-ENTITY STATUS

1. I, the undersigned, do hereby declare that:

- a. ☐ **I am an independent inventor** as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office with regard to the invention described in the patent or application identified above; OR
- b. ☐ **While I am not an inventor, I declare that rights under contract or law have been conveyed to and remain with me with regard to the invention described in the patent or application identified above.** I would qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying fees to the United States Patent and Trademark Office if I had made the invention; OR
- c. ☐ **I am the owner of the small business concern** identified below OR
☒ **I am an official of the small business concern** empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS: Hevo N.V.

ADDRESS OF SMALL BUSINESS: Nieuwstraat 12, B-2382 Poppel (BE)

If either of the boxes in item (c) is checked, I further declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.1301 through 121.1305, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. I further declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in the patent or application identified above; OR

- d. ☐ **I am an official empowered to act on behalf of the nonprofit organization** identified below:

NAME OF NONPROFIT ORGANIZATION: _____

ADDRESS OF NONPROFIT ORGANIZATION: _____

TYPE OF NONPROFIT ORGANIZATION: _____

- ☐ university or other institution of higher education; OR
- ☐ tax exempt under Internal Revenue Service Code (26 USC 501(a) and 501(c)(3)); OR
- ☐ nonprofit scientific or educational organization qualified under a nonprofit organization statute under a statute of a state of the United States of America
(name of state: _____)
(citation of statute: _____); OR
- ☐ would qualify as tax exempt under Internal Revenue Service Code (26 USC 501(a) and 501(c)(3)) if located in the United States of America; OR
- ☐ would qualify as nonprofit scientific or educational organization qualified under a nonprofit organization statute under a statute of a state of the United States of America if located in the United States of America
(name of state: _____)
(citation of statute: _____)

If Box (d) is checked, I further declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees to the United States Patent and Trademark Office regarding the invention described in the patent or application identified above.

2. The individual, concern or organization identified above has not assigned, granted, conveyed or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).
3. If the rights held by the above-identified individual, concern or organization are not exclusive, each individual, concern or organization having rights in the invention are identified below. Each such individual, concern or organization must file separate verified statements averring to their status as small entities.

***NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).**

FULL NAME: _____
ADDRESS: _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME: _____
ADDRESS: _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

4. I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small-entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Evert Bastiaan De Heus
TITLE OF PERSON (if not an owner or individual): _____
ADDRESS OF PERSON SIGNING: Nieuwstraat 12, B-2382 Poppel (BE)

SIGNATURE: X

DATE: 11-01-1999

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	De Heus, et al.)	Group Art Unit Unknown
)	
Int'l)	
Appl. No.	:	PCT/NL97/00404)	
)	
Int'l)	
Filing date	:	July 12, 1996)	
)	
For	:	STERILISATION)	
		APPARATUS)	
)	
Examiner	:	Unknown)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Preliminary to examination on the merits, please amend the above-captioned U.S.

National Phase application as follows:

IN THE SPECIFICATION

Prior to the first line of the specification on page 1, please insert --This application is the U.S. National Phase under 35 U.S.C. Section 371 of International Application PCT/NL97/00404, filed July 12, 1996.--.

On page 1 at line 28, please delete "siad" and substitute in its place --said--.

On page 6 at line 1, please delete the word "CLAIMS" and substitute in its place --

WHAT IS CLAIMED IS:--.

IN THE CLAIMS:

Please amend the claims as indicated below:

1. A [S]sterilisation apparatus for medical instruments and the like [objects] which is easy to handle and/or remove, said apparatus comprising [and which is mainly formed by] a casing provided with a double-walled sterilisation boiler [and means for performing the

sterilisation process, characterized in that the sterilisation apparatus comprises a double-walled boiler] having an inner wall and an outer wall, whereby fluid [such as demineralised water being] is present between the inner and the outer wall [by which] such that a stable temperature of the [boiler] inner wall can be achieved as well as steam generated therefrom.

2. (Amended) [A]The apparatus according to claim 1, characterized in that [at least] regulators and heating elements in said double boiler walls can provide for a stable fluid temperature.

3. (Amended) [A]The apparatus according to claim 1[or 2], characterized in that means are present for feeding steam for the sterilisation process pulsatingly into said boiler, [as well as] and means [which] can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.

4. (Amended) [A]The apparatus according to [any of preceding] claim[s] 1[-3], characterized in that means are present for setting[, **respectively**]and measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process.

5. (Amended) [A]The apparatus according to claim 4, characterized in that [the]said means are controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically[, **e.g. to an internal or external printing apparatus (printer)**].

6. (Amended) [A]The apparatus according to [any of the preceding] claim[s]1, characterized in that a [(time)] switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of said boiler, is available.

7. (Amended) [A]The apparatus according to [any or several of the preceding] claim[s]1, characterized in that [the]a sterilisation space of the boiler is provided with lateral supports for a number of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances may be placed.

8. (Amended) [A]The apparatus according to [any or several of the preceding] claim[s]5, characterized in that the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw.

10. (Amended) [A]The apparatus according to [any or several of the preceding] claim[s] 1, characterized in said double-walled boiler consists of a cylindrical sterilisation boiler [is] placed symmetrically though non-concentrically within [the]a cylindrical outer boiler, such that in the use-position the volume of the fluid or water space [down in]on the bottom of the double-walled boiler is considerably larger than [up in]at the top of the boiler.

11. (Amended) [A]The apparatus according to [any or several of preceding] claim[s] 1[-9], characterized in that said double-walled boiler consists of a cylindrical sterilisation boiler [is] placed concentrically within a cylindrical outer boiler.

12. (Amended) [A]The apparatus according to [any of preceding] claim[s]1-9]5, characterized in that [the]said process computer and [a] said sterilisation apparatus [according to claim 10 or 11] are provided in a casing in which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves [being]are present.

Please add the following claims:

13. The apparatus according to claim 1, characterized in that the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw.

14. The apparatus according to claim 1, wherein said fluid is demineralized water.

15. The apparatus according to claim 5, wherein said data read-outs are displayed to an internal or external printing apparatus.

REMARKS

The specification has been amended to include a reference to the International Application No. of the present application, PCT/NL97/00404. Additional amendments correct minor informalities in the specification.

The claims have been amended and Claims 13-15 added to more precisely claim the invention according to conventional practice before the United States Patent and Trademark Office.

Appl. No. : PCT/NL97/00404
Filing date : July 12, 1996

As a result of the amendments made herein, Claims 1-15 are presented for examination. No new matter is being added herewith. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number appearing below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 11 Jan. 1999

By: Daniel Altman

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STERILISATION APPARATUS

5 The invention relates to a sterilisation apparatus for medical instruments and the like objects, which is easy to handle and/or remove and which is mainly formed by a casing provided with a sterilisation boiler and means for performing the sterilisation process.

10 Such a sterilisation apparatus, also called a mini sterilisation apparatus, is often used in dentists' practices. The contents of the sterilisation apparatus thereby range between 10 to 50 litres and the required temperatures often are between 121 degrees C and 134 degrees C at pressures of ca. 210 kPa and 310 kPa, respectively.

15 A problem relating to this mini sterilisation apparatus is that one can barely, if at all, comply with the (international) requirement of obtaining a stable ambient temperature of the sterilisation boiler during sterilisation.

20 The invention overcomes this problem since the sterilisation apparatus comprises a double-walled boiler whereby fluid such as demineralised water being present between the inner and the outer wall by which a stable temperature of the boiler wall can be achieved as well as steam generated therefrom. This makes the sterilisation process very well manageable in a relatively small sterilisation apparatus, as also shown in practice.

25 It is thereby advantageous that at least regulators and heating elements in said double boiler walls can provide for a stable fluid temperature.

30 Advantage is offered by the embodiment according to the invention in which means are present for feeding steam for the sterilisation process pulsatingly into said boiler, as well as means which can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.

35 To make the sterilisation process occur automatically the sterilisation apparatus is provided with means for setting, respectively measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process. These means are preferably controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically, e.g. to an internal or external printing apparatus (printer).

Especially in a dentist's practice where an autoclave will be used intensively it may be desirable to provide a mini sterilisation apparatus with a (time) switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of the boiler.

5 Advantage is offered by the embodiment of a mini sterilisation apparatus according to the invention which is characterized in that the sterilisation space of the boiler is provided with lateral supports for a number of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances may be placed.

10 For effective use it is desirable that in the mini sterilisation apparatus according to the invention the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw. The screw seal is prefeably operated
15 by means of an electromotor of which the operating phases are run via said process computer.

In order to comply with the procedure required of process sterilisation, according to the invention use is made of a sterilisation boiler for incorporation in a mini sterilisation apparatus which is characterized in
20 that a cylindrical sterilisation boiler is placed symmetrically though non-concentrically within the cylindrical outer boiler, such that in the use-position the volume of the fluid or water space down in the double-walled boiler is considerably larger than up in the boiler.

It is advantageous if this sterilisation boiler is provided in a casing in
25 which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves being present.

The invention is hereinafter described by means of examples of
30 embodiments, whereby advantages and other features of the invention will become apparent.

Figure 1 shows a perspective view of a mini sterilisation apparatus;
figure 2 shows a block scheme of the most important operational
functions of the sterilisation apparatus;

35 figure 3 shows, according to a computer drawing, another embodiment of the sterilisation apparatus.

Figure 1 shows in perspective a front view of the sterilisation apparatus, in fact the casing 1 thereof, which has a mainly rectangular

shape and is made of suitable plate material. The front side shows a door 2 which can be swivelled open over more than 120 degrees and which further is well isolated against heat loss. Opening and closing the door occur automatically by activating an electrical operating button (not drawn). The opened door depicts a (inner) boiler 3 of which the space 4 in this embodiment is provided with four bearing plateaus 6, so-called norm trays, on which (wrapped) instruments or bandage substances can be transported. To that end space 4 is provided with supports 5. Door 2, which can seal sterilisation space 4, is fixed pressure-tight in the closed position by an electrically driven screw-seal 7 and cannot be opened during a sterilisation process. During a process the LCD screen 8 graphically displays the course of this process.

The sterilisation apparatus moreover comprises a process computer of which the control 9 is embodied with an indication for each process phase. The pressure, temperature, sterilisation time, drying time and possible malfunctioning are displayed digitally, eventually supported alpha-numerically or graphically. The pressure in the so-called steam generator is, as prescribed, displayed analogously on indicator 10.

Figure 2 schematically shows the sterilisation boiler 11 with various auxiliary parts and control apparatuses, which parts are described hereinafter.

It is to be noted that similar references are used for similar parts.

Boiler 11 according to the invention comprises an inner wall and an outer wall, 3 respectively 12, whereby the contents of the inner boiler range between 10 to 50 litres. Demineralised water (demi-water) 14-added to space 13 of the double boiler wall 3,12- is heated such that steam 16 is produced at the top of the boiler. Heating of the water occurs through heating elements 17,18 which have been provided in boiler space 13. For the provision of water the sterilisation apparatus comprises a water reservoir 19 onto which a floating switch 20 for level control is provided. In this arrangement a feed pump 21 is applied by means of which water down in space 13 of the double boiler wall 3,12 can be supplied. A shut-off valve 22 for pumping water for boiler space 13 is provided in the pump circuit. As already indicated above, heating elements 17,18 are provided at the bottom of boiler 3,12 by means of which the water supplied can be heated, such that steam 16 is formed at the top for the purpose of the sterilisation process. A safety switch 23 with a float embodiment for protection against dry-boiling is provided at the bottom of the boiler. A

water level controller 24 is present at the top so that the proper ratio between steam and water is always obtained. The generated steam 16 is supplied pulsatingly from boiler space 13 through a steam valve 25 into the inner boiler 3. Further, there is a temperature measuring device 26 as well as a pressure transmitter within inner boiler 3. A similar transmitter is also provided in the outer boiler 12. In figure 2 the left-hand side depicts the water and steam system and the right-hand side depicts the vacuum system. Thereby a feed line 28 is provided at the top side of the boiler, in which an aeration valve 29 is provided for feeding clean air when a vacuum is prevailing in the boiler. For the sake of certainty a sterile filter 30 provides for clean air when feeding to valve 29.

According to the invention a vacuum is drawn pulsatingly in the boiler, which is achieved by using a water-ejector system which mainly comprises an ejector 31 connected to a vacuum valve 32 which is connected through a line to inner boiler 3. A cold-water valve 33 is incorporated in the water system of ejector 31 which serves for generating a vacuum through ejector 31. Further a pressure switch 34 for measuring the water pressure is used in the line system, by which water is tapped-off from feed 35.

The following gives a brief illustration of a sterilisation process at a temperature of 134 degrees C. A process can only start if door 2 is closed, and the process begins with steaming-through whereby valves 25, 33 and 32 are opened. Valves 33 and 32 of the ejector system remain open during steaming-through. Steam valve 25 is thereby regulated at a pressure of 120 kPa within inner boiler 3. During a certain period, about 90 seconds, there is a continuous discharge of steam and air. After this period of 90 seconds steam valve 25 closes and the first vacuum pulse starts. The pulsating course of the process occurs further by successively controlling the valves concerned, the build-up of pressure as well as the time in seconds, so that the sterilisation pressure and temperature are achieved in an effective manner within the stated period. In this example a temperature of 134 degrees C to a maximum of 137 degrees C is achieved in about 15 seconds. Pressure control in the boiler is achieved by a autonomously functioning control process. However, in case during the sterilisation process the temperature and/or the pressure exceeds the maximum set value, the process is automatically broken off.

After the sterilisation traject drying of the objects present on plateaus 6 takes place by drawing a vacuum. To this end steam valve 25

is shut and cold-water valve 33 as well as vacuum valve 32 are opened, till a pressure of 10 kPa is reached. At this pressure the actual drying time starts, which lasts 5 minutes in this process (134 degrees C). After drying the boiler is aerated to relieve the vacuum. If the drying process is terminated, valves 32 and 33 are shut. When the boiler pressure lies between 95-105 kPa, aeration valve 29 shuts due to which door 2 can be opened and the sterilised objects can be removed from boiler space 4.

As stated above, the whole process takes place under the control of and monitoring by a computer and the results are displayed by means of a printing device, a so-called printer (not shown).

Figure 3 depicts another advantageous embodiment according to the invention in which in particular the water reservoir 13 has been enlarged by the positioning of inner boiler 3 relative to outer boiler 12, i.e. that the amount of water at the bottom of boiler 11 is greater than the amount at the top thereof, which may be favourable for certain sterilisation processes in view of the water-steam ratio.

The invention is not limited to the embodiments as shown and described above, since one can well imagine other arrangements of sterilisation boilers. The feature according to the invention of using a double boiler wall in a relatively small sterilisation apparatus has however resulted in the fact that such a sterilisation apparatus can comply with the highest standards, including international standards.

CLAIMS

1. Sterilisation apparatus for medical instruments and the like objects which is easy to handle and/or remove and which is mainly formed by a casing provided with a sterilisation boiler and means for performing the sterilisation process, characterized in that the sterilisation apparatus comprises a double-walled boiler whereby fluid such as demineralised water being present between the inner and the outer wall by which a stable temperature of the boiler wall can be achieved as well as steam generated therefrom.
2. Apparatus according to claim 1, characterized in that at least regulators and heating elements in said double boiler walls can provide for a stable fluid temperature.
3. Apparatus according to claim 1 or 2, characterized in that means are present for feeding steam for the sterilisation process pulsatingly into said boiler, as well as means which can also provide a pulsating vacuum in said boiler such that air in the instruments or the like objects which are to be sterilised can be removed.
4. Apparatus according to any of preceding claims 1-3, characterized in that means are present for setting, respectively measuring pressure, temperature, time and output for controlling all phases occurring within said boiler before, during and after the sterilisation process.
5. Apparatus according to claim 4, characterized in that the means are controlled by a process computer which displays various data read-outs digitally and/or alphanumerically and/or graphically, e.g. to an internal or external printing apparatus (printer).
6. Apparatus according to any of the preceding claims, characterized in that a (time) switch clock for use of "stand-by" purposes, such as for heating-up of and maintaining the temperature of said boiler, is available.
7. Apparatus according to any or several of the preceding claims, characterized in that the sterilisation space of the boiler is provided with

lateral supports for a number of standard plateaus on which instruments, whether wrapped or not, and/or bandage substances may be placed.

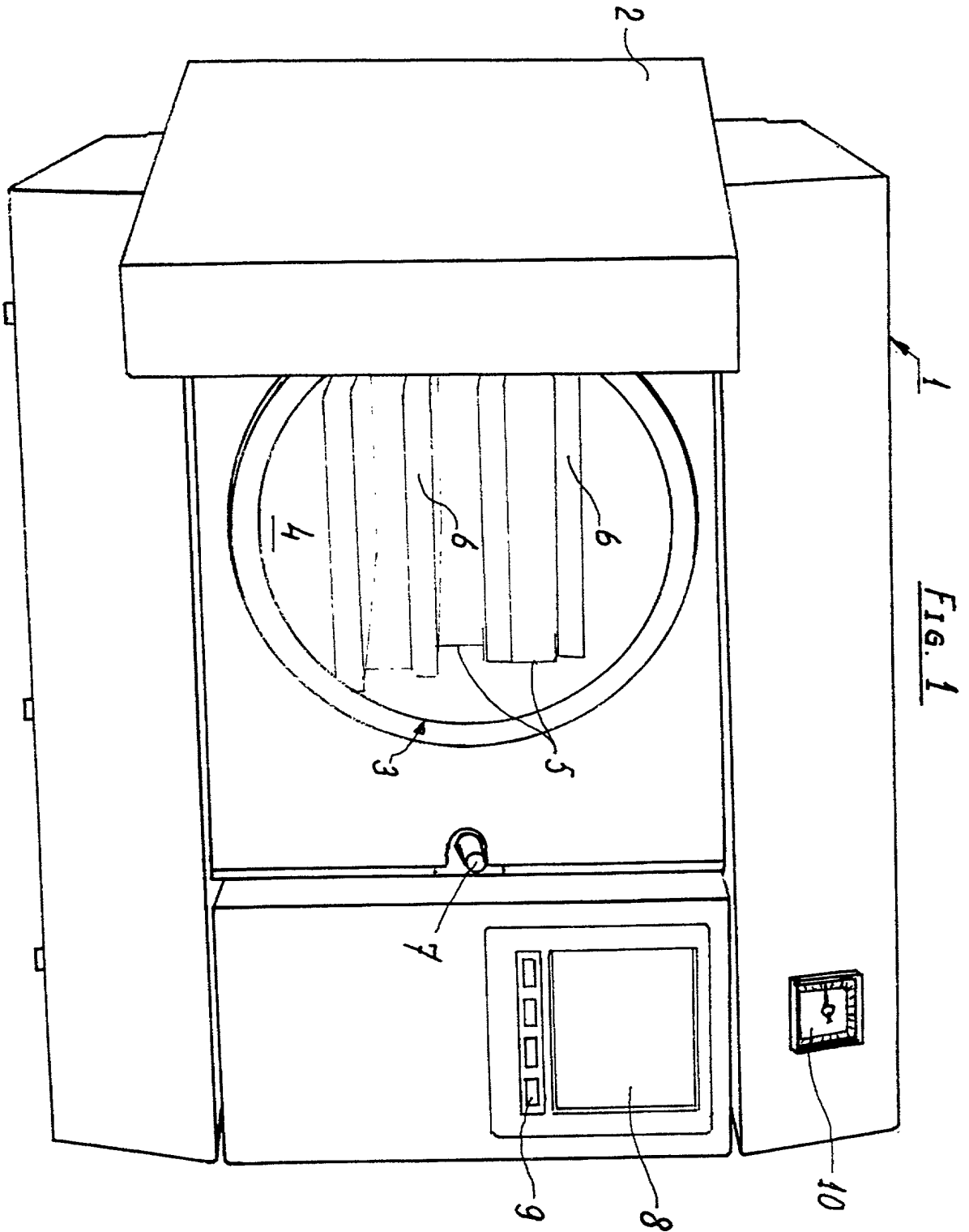
5 8. Apparatus according to any or several of the preceding claims, characterized in that the front or feed side of the boiler can be sealed pressure-tight by means of a heat-isolating hinged door provided with an incorporated nut whereby the casing to that end is provided with a swivelable hermetically sealing screw.

10 9. Apparatus according to claim 8, characterized in that the screw seal is operated by means of an electromotor of which the operating phases are run via said process computer.

15 10. Apparatus according to any or several of the preceding claims, characterized in that a cylindrical sterilisation boiler is placed symmetrically though non-concentrically within the cylindrical outer boiler, such that in the use-position the volume of the fluid or water space down in the double-walled boiler is considerably larger than up in the boiler.

20 11. Apparatus according to any or several of preceding claims 1-9, characterized in that a cylindrical sterilisation boiler is placed concentrically within a cylindrical outer boiler.

25 12. Apparatus according to any of preceding claims 1-9, characterized in that the process computer and a sterilisation apparatus according to claim 10 or 11 are provided in a casing in which also the fluid reservoir with corresponding pump, control appendages, a dry-air connection and a connection to a vacuum line with valves being present.



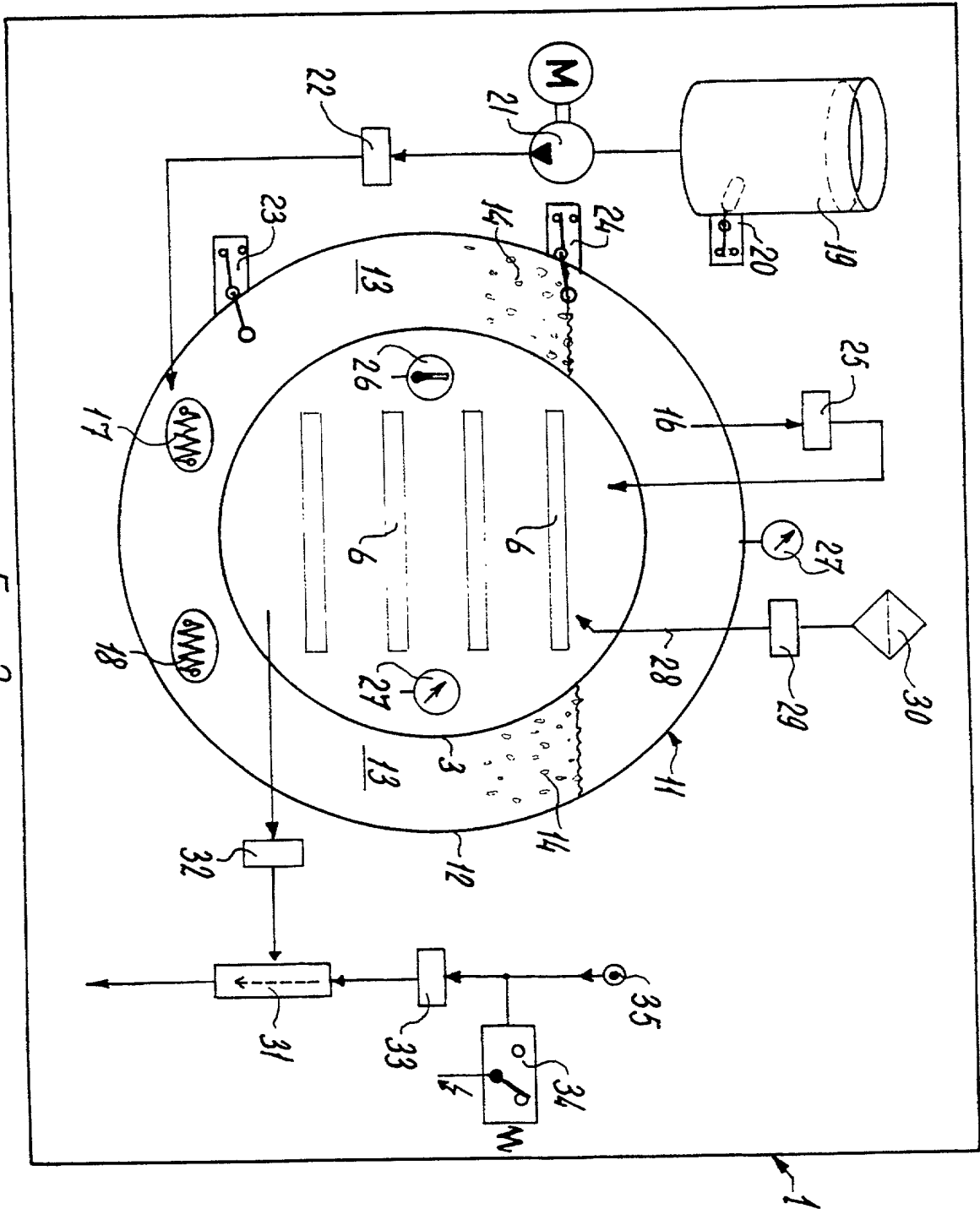


FIG. 2

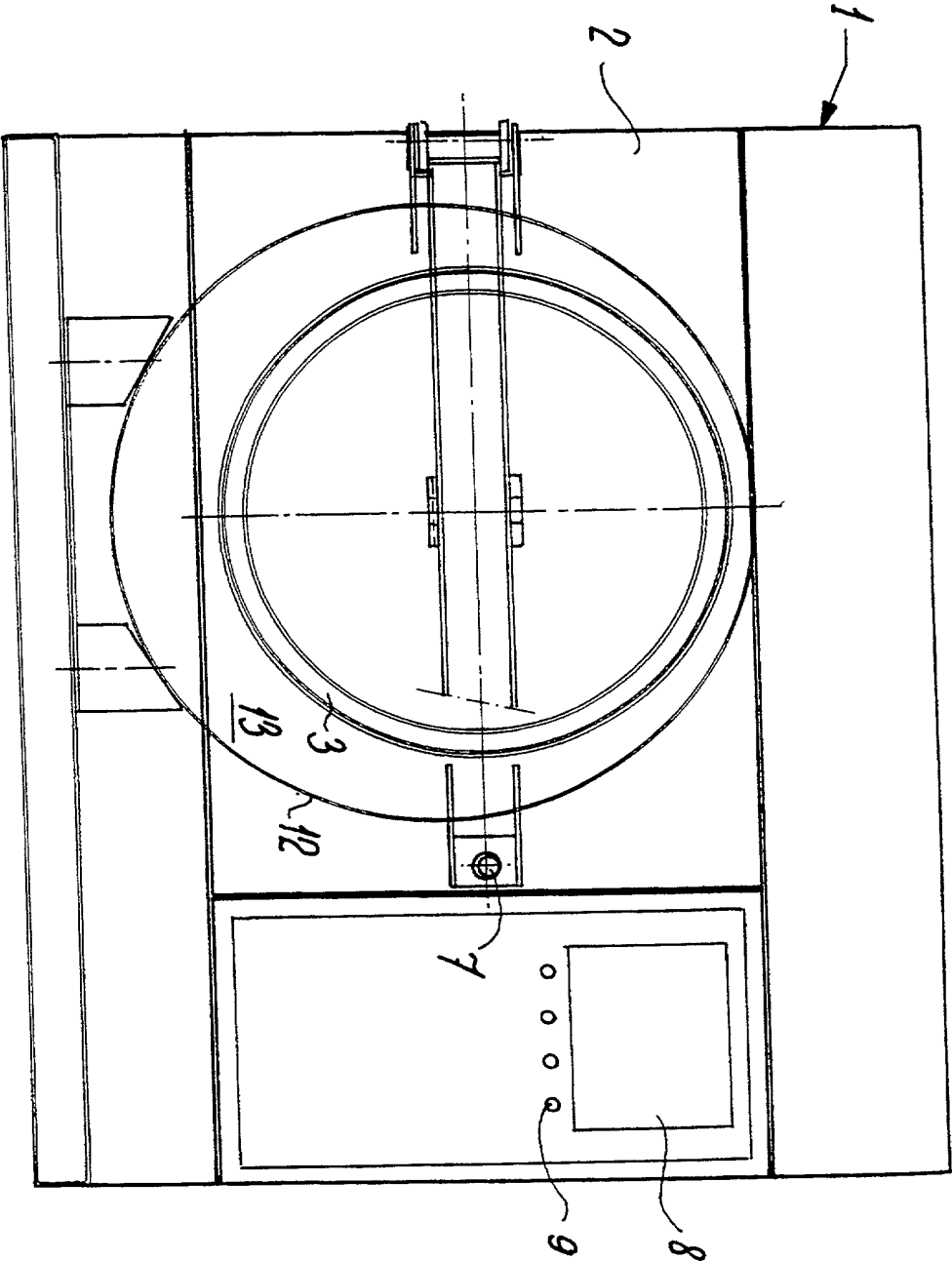


Fig. 3

**DECLARATION AND POWER OF ATTORNEY - USA PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **STERILISATION APPARATUS**, the specification of which:

- (a) ☐ is attached hereto; or
- (b) ☐ was filed on _____ as ☐ Application No. 0 / _____ or ☐ Express Mail No., as Application No. not yet known _____ and was amended on _____ (if applicable); or
- (c) ☒ was described and claimed in PCT International Application No. **PCT/NL97/00404** filed on **July 9, 1997**.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56;

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) listed below and have also identified below any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed for the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 U.S.C. § 119
Netherlands	1003576	12 July 1996	<input checked="" type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application(s)

Application No.: _____ Filing Date: _____ Status: _____

POWER OF ATTORNEY: I hereby appoint the registrants of Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, Sixteenth Floor, Newport Beach, California 92660, Telephone (949) 760-0404, **Customer No. 20,995**.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole inventor: Evert Bastiaan De Heus

Inventor's signature [Signature] Day 11 Month 01 Year 1999

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